

# EXHIBIT 16

**UNITED STATES DISTRICT COURT**  
**NORTHERN DISTRICT OF OHIO**  
**EASTERN DIVISION**

IN RE NATIONAL PRESCRIPTION

OPIATE LITIGATION

*This document relates to:*

*The County of Summit, Ohio, et al. v. Purdue Pharma*  
*L.P., et al., Case No. 18-OP-45090*

MDL 2804

Case No. 17-md-2804

Hon. Dan Aaron Polster

Report of David S. Egilman MD, MPH

March 25, 2019

## 2 BACKGROUND AND QUALIFICATIONS

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My name is Dr. David Egilman. I am a medical doctor and Clinical Professor of Family Medicine at Brown University. I am board certified in Internal Medicine and Preventive-Occupational Medicine. My *curriculum vitae* [Egilman CV hereto attached as **Exhibit A.1**] sets forth more fully my qualifications.

I received a Bachelor of Science degree in Molecular Biology and a degree in Medicine at Brown University. [Egilman CV at 1] I then completed my three year residency in internal medicine at the University of Rochester. [Egilman CV at 1] I helped start a program focused on women's health. I completed NIH's three-year Epidemiology Training Program. [Egilman CV at 1-2] The first year of this program involved training at the Harvard School of Public Health (HSPH), where I was awarded a Master's Degree in Public Health. [Egilman CV at 1-2] At Harvard, I studied industrial hygiene and toxicology; epidemiology; statistics; occupational medicine and law; public policy with respect to occupational and environmental hazards; areas that relate to the specialty of preventive medicine, including education, product design changes and substitution; warnings and risk communication, including regulatory approaches to control; the tort system; environmental law; Food and Drug Administration (FDA) and OSHA law; and the Consumer Product Safety Commission (CPSC). One course that I completed during the program covering various legal and regulatory approaches to control of health hazards was a joint course offered by the Harvard Law School, the Harvard School of Public Health, and the MIT Business School. I spent the second two years of the National Institutes of Health (NIH) Epidemiology Training Program at NIOSH. As part of my assignment I received the training in epidemiology and surveillance provided by the Centers for Disease Control to Epidemic Intelligence Service officers. At NIOSH, I received training in the law as it applied to NIOSH and OSHA medical officers. I was responsible for implementing parts of the OSHA Act relevant to investigation of worker health. I received training in risk communication and warnings at NIOSH. At NIOSH, I received training in industrial hygiene techniques, conduct of epidemiologic studies, and risk analysis -- particularly as it applied to carcinogens and dose assessment. I designed implemented small and large epidemiological studies. I participated in industrial hygiene sampling and became familiar with industrial hygiene monitoring for asbestos and other toxic exposures. While at NIOSH, I completed the NIOSH residency in occupational medicine in 1984. [Egilman CV at 1] At NIOSH I was a uniformed officer of the U.S. Public Health Service. While at NIOSH, my responsibilities included education of workers, employers and members of the public regarding health hazards. I provided this information through a variety of vehicles, including written reports, conferences, mass meetings and face-to-face conversations. NIOSH and the CDC provided training on the mechanisms of effective communication. I completed a third residency in preventive medicine in 1993. [Egilman CV at 1]

Occupational Medicine is the branch of medicine that deals with the prevention and treatment of diseases and injuries that occur as a result of exposure to chemical substances. This specialty deals with the toxicological effects of exposures to chemical substances on the body. The fundamental aspect of this specialty is the determination of which exposures cause disease, and how they do so. My educational and professional background, training

at HSPH and NIOSH, and teaching and publications provide the basis of my expertise in warnings.

I have extensively studied the role of warnings in preventing illnesses and the current and historical techniques for providing warnings. I have published two chapters in the major textbook relating to warning and risk communication. [Egilman CV at 13: Chapter Two "A Brief History of Warnings," and "Consider The Source: Warnings And Anti-Warnings In The Tobacco, Automobile, Beryllium, And Pharmaceutical Industries" in Wogalter Ed., Warnings and Risk Communication]

My first chapter in the book on Warnings and Risk Communication, (the first full chapter in the book) dealt with the history of warnings; the second addressed the adverse effects of marketing on public health, focusing particularly on false reassurance given by product manufacturers to consumers. Both chapters dealt with issues that related to FDA regulatory authority. Some of my publications have dealt with FDA regulations and I cover FDA-related issues in my course. [Egilman CV at 2, 13, & 19]

I also ran a clinic for 12-13 years, treating patients and consulting in occupational medicine for large and small companies. I treated patients with pain from cancer and chronic non-malignant pain and at times prescribed opioids in my practice. [Egilman IMS Data hereto attached as **Exhibit A.2**]

I am licensed to practice medicine in Massachusetts, Rhode Island, and Mississippi. I have published over 100 papers, including 50 original publications in peer-reviewed journals and 78 presentations. I have authored peer-reviewed publications on epidemiology and causation; regulatory science; warnings, anti-warnings, and risk communication; the development of the corporate, medical and scientific communities' knowledge of the health hazards; and corporate influence on science and regulation.

The Asbestos Disease Awareness Organization (ADAO) awarded me the Irving Selikoff Lifetime Achievement Award for my academic contributions to the prevention of asbestos disease. [Egilman CV at 3]

I have taught several courses at Brown University, including the Development of Medical and Scientific Knowledge in the 20th Century; and Science and Power: A Bioethical Inquiry, and currently teach a course in the Brown School of Public Health called, "Science and Power – The Corruption of Public Health." This course deals specifically with the issues outlined in this report: the history of the development of knowledge regarding the health hazards; FDA regulations; warnings and risk communication, including corporate knowledge of health effects of products; the history of the development of government regulations on occupational, consumer and environmental safety; and the history of the development of contemporaneous appropriate public health responses to information regarding the adverse health effects of products on users, including education of product users and product redesign (state of the art). In my course, I compare the medical and scientific information available to the companies with that available to the medical and scientific community.

I have also published on these topics. I have also taught a two-year course for medical students that covered medical ethics, community approaches to public health, and health education.

I served, for over 10 years, as a preceptor to residents in Family Medicine and medical students, supervising the care of patients. I served for 9 years as the Editor in Chief of a major journal: The International Journal of Occupational & Environmental Health. [Egilman CV at 2]

On two occasions I testified before congressional sub-committees on the issues relating to informed consent and corporate responsibility to inform members of the public about health hazards. My testimony concerned the history of informed consent, warnings, and research ethics. In addition, I have published two papers on the topic of the history of the development of informed consent. I was a board member of Citizens for Responsible Care in Research from 1997- 2009. I am currently a board member of The Alliance for Human Research Protection (AHRP). These non-governmental organizations (NGO) deal with the ethical conduct of research.

I have reviewed the history of warnings from the published literature, and from internal corporate documents and organizational documents. I presented several papers on warnings. I teach about warnings at Brown University, including FDA drug-related warnings. I testified before Congress on the history and development of informed consent, as well as on current informed consent practices. I have been accepted as an expert by the court in Keenan v. Parke-Davis et al. PC 84-1667 (Rhode Island) on the issue of warnings and FDA policy. I have also been accepted as a witness on issues that relate to FDA warning policy in the case of Vassallo v. Baxter Healthcare Corporation, 428 Mass. 1 (1998). My affidavit on medical epistemology was cited by the court. I have reviewed corporate documents specifically addressing warning practices throughout this century. I have studied the efficacy of warnings.

Along with my colleague, Susanna Bohme, I co-authored two chapters in a textbook on the history of warnings: Egilman D.S., Bohme S.R. "A Brief History of Warnings" and "Consider the Source: Warnings and Anti-Warnings in the Tobacco Beryllium, Automobile and Pharmaceutical Industries," Handbook of Warnings, ed. Michael Wogalter Mahwah, NJ: Lawrence Erlbaum Associates, 2006. In November of 2004, I presented a lecture at the American Public Health Association Conference entitled, "Occupational Warnings: Protecting People or Protecting Profit?" In addition, in July of 2004 at the Center for Science in the Public Interest (CSPI) conference, I presented a lecture on "The Suppression of Science: How Corporate Interests Hide the Truth." In this talk, I spoke of the need to adequately warn doctors and the public about the health risks of exposure to products, about FDA regulations, and about corporate codes of conduct and ethical standards.

I have presented at the annual American Public Health Association conference off-label marketing and hiding addiction risks. (Egilman DS and Falender J. OxyContin: How Profits Took Priority over Public Health. APHA, Nov 2004.) In February 2013, I presented to the FDA about OxyContin's 12-hour dosing regimen as a contributing cause of opioid addiction. [FDA Presentation Slides and Transcript hereto attached as **Exhibit A.3 and**

**Exhibit A.4]** I have authored a number of articles and presentations pertaining to medical and business warnings issues. (See attached CV for complete list of publications and presentations.)

- Writings and presentations explicitly dealing with warnings and disclosure in business and scientific research and publishing:
  - Angell, M et al. Letter to the Editor [Journal Should Strengthen Conflict of Interest Disclosure Policy] *Nature Neuroscience* 6: 10, October 2003.
  - Egilman, D.S., Ehrle, L.H. Handling Conflicts of Interest between Industry and Academia. *JAMA* 289, June 25 2003: 3240.
  - Egilman, D., Hornblum, A., Letter to the Editor: Guinea Pigs Behind Bars, *The Boston Globe*, Monday, November 29, 1999.
  - Egilman, D., Wallace, W., Stubbs, C., and Mora-Corrasco, F. "Ethical Aerobics: ACHRE's Flight from Responsibility." *Accountability in Research* Vol. 6, pp. 15-61, 1998.
  - Egilman, D., Reinert, A.: What Is Informed Consent? *Washington Post*, January 14, 1994: P 24.
  - Egilman, D., Ethics of Mandatory Masturbation (letter), *JOM*, 30;12:992, December 1988.
  - Egilman, D.S., Written Testimony submitted to the US Senate Subcommittee on Antitrust, Competition Policy and Consumer Rights Hearing, "Hospital Group Purchasing: Has the Market Become More Open to Competition?" July 16, 2003.
  - Egilman, David: Oral Testimony Before the President's Advisory Committee on Human Radiation Experiments, July 17, 1995.
  - Egilman, David: Oral Testimony Before the President's Advisory Committee on Human Radiation Experiments, February 1995.
  - Egilman, D., Wallace, W., Stubbs, C., and Mora-Corrasco, F. "A Little Too Much of the Buchenwald Touch? Military Radiation Research at the University of Cincinnati, 1960-1972." *Accountability in Research* Vol. 6, pp. 63-102, 1998.
  - Egilman, David: International Health Work: First Do No Harm, Family Medicine Grand Rounds, Memorial Hospital of Rhode Island, Feb. 1991.
  - Bailar JC, Ballal SG, Boback M, Castleman B, Heng LC, Cherniack M, Christiani D, Cicoletta A, Fernandez de D'Pool J, Egilman DS, et al. (Special Contributions) FIOH-sponsored Newsletter Misrepresents Asbestos Hazards in Zimbabwe. *Int J Occup Environ Health* 12(3):254-258, Jul-Sept 2006.
  - Egilman DS. Ford, General Motors, Chrysler, Asbestos and a "Sane Appreciation of the Risks" (Editorial). *Int J Occup Environ Health* 15(1):109-110, Jan-Mar 2009.
  - Egilman DS and Bohme SR. Vioxx Marketing: Merck's Failure to Warn. *International Ergonomics Association 2006 Conference Proceedings*.

- Bohme SR and Egilman DS. Pharmaceutical Warnings and “Direct to Consumer” Marketing. International Ergonomics Association 2006 Conference Proceedings.
- Bohme SR and Egilman DS. Occupational Warnings: Protecting People or Protecting Profit. APHA, Nov 2004.
- Egilman DS. Panel Member: From Practice to Science: How Application Guides Warning Research. International Ergonomics Association Conference, Jul 2006.
- Other writings and presentations, considering issues relevant to the fields of medical and business practices, including industry influence on research, attorney misconduct in procuring clients, and marketing of products that injure workers and/or consumers:
  - Egilman, D.S., Fehnel, C., Bohme, S.R. Exposing the “Myth” of ABC: A Critique of the Canadian Asbestos Mining Industry-McGill Chrysotile Studies. *Amer J Ind Med* 44:5, 2003.
  - Egilman, D.S., Bagley, S., Biklen, M., Golub, A.S., Bohme S.R. The Beryllium “Double Standard” Standard. *International Journal of Health Services* 33:4, 2003.
  - Egilman, D.S., Bagley, S., Connolly, S., Letter to the Editor: Anything But Beryllium: The Beryllium Industry’s Corruption of Safety Information, *Am. J. Ind. Med.*, 42:3, September 2002.
  - Egilman, D.S., Asbestos Screenings, *Am. J. Ind. Med.*, 42:2, August 2002.
  - Egilman, D., Walta, M., Letter to the Editor: Breast Implant Verdicts Resulted From Corporate Misconduct and Legitimate Science, *Am. J. Pub. H.*, 89:11 1763-1764, November 1999.
  - Egilman, D., Hom, C., Commentary: Corruption of the Medical Literature: A Second Visit, *Am. J. Ind. Med.*, 34:4 401-404, October 1998.
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  - Durand, K. and Egilman, D., Possible Corruption Of IH Literature By DuPont: The Imron Respirator Studies, *Am Ind. Hyg.. Assoc. J.* 56:817-825, August 1995.
  - Egilman, D., Reinert, A.: The Origin and Development of the Asbestos Threshold Limit Value: Scientific indifference and corporate influence. *Int. J. Health Serv.* 25:667-696, 1995.
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  - Egilman, D., The emperor has no clothes: TLVs and Corporate influence, *Am Ind. Hyg. Assoc. J.*, 187-188, March 1990.
  - Egilman, D.S., Evidence of Continued Corruption of the Epidemiological Literature, APHA, November 2002.
  - Egilman, D.S., Tobacco Marketing as an Anti-warnings Program, APHA, November 2002.
  - Egilman, D.S., Connolly, S., Golub, A., QAMA/McGill Corruption of the Epidemiologic Literature on Canadian Asbestos Mining, IEA World Conference of Epidemiology, August 2002.



- Egilman, D.S., Bagley, S., The Corporate Corruption of Epidemiology: The Asbestos, Beryllium, Tobacco Industries and the Role of Attorneys and Public Relations Firms, IEA World Conference of Epidemiology, August 2002.
- Egilman, D.S. Role of Insurance Companies in Industrial Health: Example of the Asbestos Tragedy, APHA, October 2001.
- Participant, Institute of Medicine, Division of Health Sciences Policy, Town Meeting on Clinical Research in the Public Interest, National Academy of Sciences, Washington, D.C. July 10-11, 1997.
- Kate Duran and Egilman, David: Corruption of IH Literature by Chemical Companies, APHA, Nov. 1991.
- Egilman, David, and Alexander Reinert: Corruption of the Asbestos Epidemiological Literature, APHA, Nov. 1991.
- Egilman, David: The Making of an Occupational/Environmental Disaster: The Corruption of the Asbestos Literature, Family Medicine Grand Rounds, Memorial Hospital of Rhode Island, Mar. 1991
- Egilman DS. Suppression Bias at the Journal of Occupational and Environmental Medicine. *Int J Occup Environ Health* 11(2):202-204, Apr-Jun 2005.
- Egilman DS and Bohme SR, Guest Editors. Over a Barrel: Corporate Corruption of Science and Its Effects on Workers and the Environment. *Int J Occup Environ Health* 11(4):331-337, Oct-Dec 2005.
- Egilman DS and Billings MA. Abuse of Epidemiology: Automobile Manufacturers Manufacture a Defense to Asbestos Liability. *Int J Occup Environ Health* 11(4):360-371, Oct-Dec 2005.
- Bohme SR, Zorabedian J, and Egilman DS. Maximizing Profit and Endangering Health: Corporate Strategies to Avoid Litigation and Regulation. *Int J Occup Environ Health* 11(4):338-348, Oct-Dec 2005.
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- Egilman DS and Howe S. Against Anti-health Epidemiology: Corporate Obstruction of Public Health via Manipulation of Epidemiology. *Int J Occup Environ Health* 13(1):118-124, Jan-Mar 2007.
- Krumholz HM, Ross JS, Presler AH, and Egilman DS. What Have We Learnt from Vioxx? *BMJ* 334(7585):120-123, Jan 20, 2007.
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- LaDou J, Teitelbaum DT, Egilman DS, Frank AL, Kramer SN, and Huff J. American College of Occupational and Environmental Medicine (ACOEM): A Professional Association in Service to Industry. *Int J Occup Environ Health* 13(4):404-426, Oct-Dec 2007.
- Ross JS, Hill KP, Egilman DS, and Krumholz HM. Guest Authorship and Ghostwriting in Publications Related to Rofecoxib: A Case Study of Industry Documents from Rofecoxib Litigation. *JAMA* 299(15):1800-1812, Apr 16, 2008.



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- Egilman DS, Ardolino EL, Howe S, and Bird T. Deconstructing a State-of-the-Art Review of the Asbestos Brake Industry. *New Solut* 21(4):545-571, 2011.
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- Bohme SR and Egilman DS. Beyond Reputation: Debate on the Role of Corporate Influence in Occupational and Environmental Medicine. *New Solut* 18(3):317-324, 2008.
- Egilman DS. Seeding Trials: Just Say No (Letter). *BMJ* 339:b4527 Nov 2, 2009.
- Egilman DS and Druar NM. Corporate versus Public Interests: Community Responsibility to Defend Scientific Integrity (Editorial). *Int J Occup Environ Health* 17(2):181-185, Apr-Jun 2011.
- Egilman DS and Bohme SR. Corporate Corruption of Science and its Effects on Workers and the Environment. *Chain Reaction – The National Magazine of Friends of the Earth Australia* 121:20-23, Jul 2014.
- Egilman DS and Tran T. A Commentary on Roggli’s “The So-Called Short-Fiber Controversy”. *Int J Occup Environ Health* DOI: 10.1080/10773525.2016.1153866, 2016.

- Egilman DS and Bohme SR. The suppression of science: How corporate interests hide the truth and how to stop them. Center for Science in the Public Interest Conference, Jul 2004.
- Egilman DS and Falender J. OxyContin: How Profits Took Priority over Public Health. APHA, Nov 2004.
- Egilman DS and Tran T. Manipulation in Data Presentation to the U.S. Food and Drug Administration (FDA) and the Public by DePuy Synthes. APHA, 2015.
- Fassler E, Steffen J, Egilman D. Corporate Manipulation of Law and its Impact on Chronic Disease. APHA 2018 Annual Meeting & Expo, San Diego, CA. Nov 10-14, 2018.

I have reached the conclusions stated below to a reasonable degree of medical probability based on my review of the medical and scientific literature, corporate documents, depositions and on my years of training and clinical experience.

**7.27 OPINION – CEPHALON’S ACTIQ WAS NOT INDICATED FOR, BUT WAS MARKETING OFF LABEL FOR MINOR PAIN.**

See Exhibit B.27 hereto attached.

**7.28 OPINION – CHRONIC LONG ACTING OPIOIDS ARE NOT INDICATED FOR TREATMENT OF OSTEOARTHRITIS, LOW BACK PAIN OR FIBROMYALGIA. OPIOIDS ARE NOT INDICATED AT ALL FOR RHEUMATOID ARTHRITIS OR FIBROMYALGIA.**

See Exhibit B.28 hereto attached.

**7.29 OPINION – CORPORATE INTEGRITY AGREEMENTS INDICATING THAT EACH OF THESE COMPANIES VIOLATED FDA RULES.**

See Exhibit B.29 hereto attached.

**7.30 OPINION – DOCTORS ON THE “VENTURE’S” PAYROLL ADMITTED THAT PSEUDOADDICTION DESCRIBES BEHAVIORS ‘CLEARLY CHARACTERIZED AS DRUG ABUSE’ AND PUT THE “VENTURE” AT RISK OF ‘SANCTIONING ABUSE.’**

See Exhibit B.30 hereto attached.

**7.31 OPINION – FORMULARY ACCESS IS KEY TO SALES - FORMULARY RESTRICTIONS HAD THE LARGEST INFLUENCE ON PRESCRIBING - PURDUE USED INFLUENCE TO GET OXYCONTIN ON MAYO CLINIC FORMULARY.**

See Exhibit B.31 hereto attached.

**7.32 OPINION – GETTING ON THE FORMULARY IN OHIO WAS IMPORTANT TO JOHNSON & JOHNSON.**

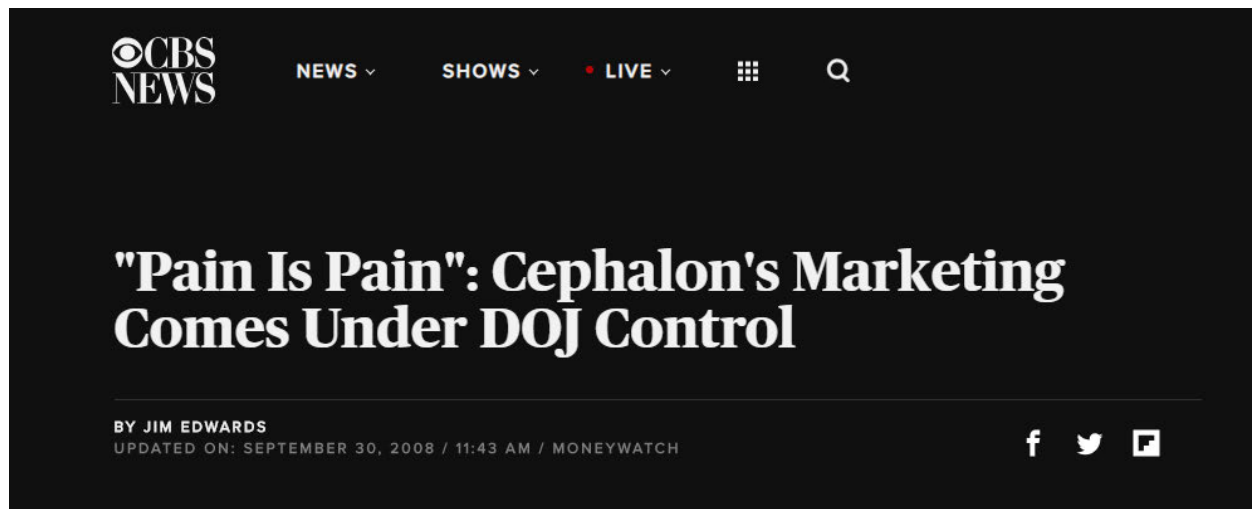
See Exhibit B.32 hereto attached.

## OPINION —CEPHALON'S ACTIQ WAS NOT INDICATED FOR, BUT WAS MARKETING OFF LABEL FOR MINOR PAIN.

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Basis

<https://www.cbsnews.com/news/pain-is-pain-cephalons-marketing-comes-under-doj-control/>



Cephalon agreed yesterday to a \$444 million settlement with the Department of Justice that will control its marketing of Actiq, Provigil and Gabitril. (Scroll to the bottom of this page if you want to read the prosecutors' documents describing the scale of wrongdoing at the company.)

The company admitted that it promoted Actiq for various types of pain, under the mantra "Pain is pain," even though it was only approved for cancer pain. As for Provigil, the ~~company promoted that drug to combat any kind of sleepiness, and not just diagnosed narcolepsy for which it is approved.~~

A doctor associated with similar activity was caught by the FDA doing something like this last year.